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REGULATING THE POLICIES OF MEDICINES IN SMALL STATES WITH SPECIAL REFERENCE TO THE MALTESE ISLANDS

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SECTION 1: INTRODUCTION

1.1 Background

The Barbados Programme of Action concluded that "Small island developing states are limited in size, have vulnerable economies and are dependent both upon narrow resource bases and on international trade, without the means of influencing the terms of that trade" (United Nations General Assembly, 1994: 4). As a small island state, Malta experiences limitations in various sectors, and upon the accession into the European Union (EU), Malta had to adopt the EU pharmaceutical legislative framework which is applied on all EU member states. The adoption of EU legislation sets a legal framework for all member states and this requires changes and adaptability by the concerned member state, although the framework may not be the best one for the requirements of each member state in all aspects. Following accession into the EU, there was a lot of criticism that EU accession had a negative impact on the regulation of medicines in Malta and some stakeholders were of the opinion that Malta could have carried out negotiations in a different way and adopted policies which were adequate for its particular small size (The Medical Association of Malta, 2006).

1.2 Research Aims and Questions

The aim of this dissertation was to study the impact and to identify the major benefits and constraints regarding Medicines Policy on medicines and pharmaceutical activities, which resulted from Malta's accession into the EU. In this respect, what were the advantages and disadvantages for Malta when the medicinal *acquis* of a 'larger community' was adopted, and Malta joined the 'single market'.

The author intended to study the situation of other small states in the EU and the European Economic Area (EEA), with respect to Medicines Policy and compare the situation in these countries with the pharmaceutical sector in Malta after the implementation of EU Legislation. The research questions were:

- What were the benefits and constraints regarding Medicines Policy for Malta upon EU accession?
- Does the 'small size' of an EU/EEA Member State have an implication on the impact experienced following the adoption and implementation of EU legislation regarding Medicines Policy?
- Would Malta have benefited from a different model of medicines regulation which was more adapt to its special characteristics?

1.3 Framework for Medicines Policies

Medicines Policies are complex and cover many different areas which are often inter-related. One of the main challenges for this dissertation was how to comprehensively represent such a vast subject. It was immediately evident that there was a need for a framework to describe and illustrate Medicines Policy and also to allow comparison with the situations in different countries.

Different models for the regulation of medicines exist globally, and during the Consultation on the Models for Regulatory Decision Making which was held in November 2006 in Geneva, the World Health Organisation (WHO) (2006a) stated that the regulation of medicines is conditioned by the size of the pharmaceutical market, not disregarding different cultures, political and economical factors. Appropriate systems and structures of medicine regulation have to be in place, but however medicine regulatory procedures are still largely unsuccessful due to scarcity of technical and human resources, and the WHO (2006a) added that there are various reasons as to why regulatory authorities have to rely on other authorities for the assessment of medicine for registration.

The most comprehensive standardised and official framework identified to depict Medicines Policy was that of the WHO, and this was adopted as the framework for this study.

SECTION 2: DISCUSSION AND CONCLUSIONS

2.1 Limitations of the Study

A major limitation to this study was the lack of availability of information regarding the different aspects of the NMP in small states outside the EU.

2.2 The Benefits and Constraints for the NMP in Malta upon EU Accession

While the impact of the implementation of EU legislation has been classified into benefits and constraints this classification is subjective and highly dependent on the perspective adopted. For example certain constraints which lead to lack of availability of medicines on the local market can result in a competitive advantage to suppliers. Wherever possible in this discussion the alternative points of view were considered however it must be borne in mind that the results were mainly based on the replies of the respondents.

2.2.1 Benefits of EU legislation for Malta

From a public health point of view, the main benefit for Malta was that as a result of EU accession, Malta now has a solid medicines regulatory framework, something which was not achieved prior to EU accession. For successful medicines regulation, legislation is an essential tool which provides the basis to address public health needs (WHO, 2003). The scope of the EU legislation for pharmaceuticals is to safeguard public health whilst promoting the freedom of movement of medicines (EC, 2002). Few markets are heavily regulated as the pharmaceutical market and this is because medicines regulation entails the concern to secure health policy objectives whilst protecting public health and to guarantee the access to good quality, safe and efficacious medicines (Saltman *et al*, 2002).

Another direct benefit of regulation is that now there is constant monitoring of issues of safety of medicines and that if there are problems remedial action is taken immediately. Before Malta acceded into the EU, pharmaceutical legislation covered mainly pharmacy activities and importation of medicines required only a Certificate of Pharmaceutical Product (CPP). This was not enough to ensure that the medicines available on the Maltese market were of good quality, safe and efficacious. A number of attempts to introduce a system for medicines registration in Malta failed, and in the study, 'The Managed Entry of New Drugs into a National Health Service: a Case Study for Malta', Vella Bonanno (2003) confirmed that during interviews with medical representatives prior to EU accession, some individuals stated that medicines registration was a bureaucratic process and they were glad that Malta had no legislation and had found an alternative system of registration for medicines.

Another benefit brought up by participants was that EU legislation has helped to control abuse. Within the EU regulatory network there is strong monitoring and enforcement and this ensures that there is consistent implementation of legislation and rules are not bent or changed according to circumstances, something which is quite risky particularly within a small population. The new legislation empowers enforcement, whereas in the past, before Malta acceded into the EU, enforcement was minimal due to the fact that since Malta is very small there is risk of familiarity.

Without any doubt, the pharmaceutical manufacturing industry in Malta has proved to be one of the sectors which reaped the positive influences of the EU legislation, not only in giving new job opportunities (particularly for specialised technical jobs), but also in a flourishing pharmaceutical

industry. Participants in this study have indicated that prior to EU accession the local pharmaceutical industry encountered many problems, since there was no regulatory body, especially for the export sector. Due to the establishment of the Medicines Authority which has achieved international credibility, Malta's pharmaceutical industry now can make use of the local regulatory authority especially when it comes down to exporting medicines since licences are now issued locally and are recognised within the whole of the EU and also in countries with a mutual agreement.

2.2.2 Constraints of EU legislation for Malta

Although many stakeholders and interested parties in the pharmaceutical sector stated that they were in favour of some type of regulation, stakeholders in this study emphasised that the main negative impacts of the EU pharmaceutical legislation were due to the fact that problems were not appropriately addressed prior to accession. Stakeholders strongly believed that many of the constraints which resulted from the implementation of EU legislation could have been avoided. Stakeholders emphasised that there should have been much more consultation with them and that they should have been more directly involved in the discussions to avoid the negative impacts.

This study showed that the implementation of the EU pharmaceutical legislation has left its main negative impacts on the availability and affordability of medicinal products on the local market. These two factors are highly linked, as reduction in the number of products on the market leads to decreased competition, thus increases in prices. Governments have a responsibility to ensure that the supply systems of medicines in both the private and public sectors are efficient and allow easy access to medicines.

The implementation of EU legislation has been considered as a barrier to the availability of medicines on the local market. Participants in this study have shown their distress by stating that after EU accession medicines availability has become a concern for the patient, the pharmacist and doctor. Barriers to entry in the supply system pose threats to the medicines availability on the market and contributing factors include brand loyalty, patents and lengthy medicines approval for marketing authorisations amongst others (Saltman *et al*, 2002). Factors being claimed as leading to the decrease in availability of products included the fact that foreign companies are not interested in spending so much money to register and maintain medicine registrations for such a small market. The work and the expenses of the infrastructure required for regulation are too high compared to the volume of sales. Participants explained that the resources required to maintain the regulatory framework for Malta is the same as for larger countries, however the total profits are lower. They explained that the extra expenses incurred for non-productive work or for compliance with regulatory requirements had to be absorbed by someone and this frequently resulted in increase in prices. Participants also added that due to the smallness of our country business conflicts might occur and although it would be more financially viable to have certain services which require high fixed costs for set up such as repackaging facilities centralised at a few service providers most wholesale dealers are choosing to have their own set up to repackage their products. It was also pointed out that not all price increases were due to increases in cost. Some stakeholders may have taken the opportunity of the transition to increase their profits.

The small size of the local market does not make it feasible for Marketing Authorisation Holders (MAH) to set base in Malta and the great majority of MAHs are not present locally but are just represented by a local agent. Local agents often represent more than one MAH and this may lead to conflicts of interest. At times foreign MAHs find it difficult to establish local contacts, and this is another reason as to why Malta is being excluded from certain registration procedures such as the MRPs.

'Old products' which were not registered could no longer be placed on the market, thus over a short period of time a significant number of these products (after accession the number of products which could be placed on the market went down from around 8000 to 1760) vanished from the market and this was of great concern. This constraint had a direct impact on patients and also effected pharmacists and doctors. Patients who were stabilised on certain medicines had to change to an alternative preparation (which was generally more expensive). Participants in this study have also pointed out that some clinical practices and norms in the use of medicines had to be changed.

Participants strongly felt that there is increased use of the internet by patients to obtain information and to buy medicines over the internet. Participants felt that the internet can be beneficial in providing information, however the internet can also be a negative source in misleading individuals who seek information or who purchase medicines from the internet. The lack of one to one contact with the pharmacist can invite an individual to buy medicines which are either not available on the local market or perhaps for a better price from the internet. The main danger of buying medicines over the internet is that there is no guarantee of the source of the medicine and there is a high risk that the medicine supplied is counterfeit. The issue of counterfeit medicines has now become a global public health crisis because adults and children have suffered disability, injuries and even deaths from counterfeit medicine. The problem is not new or unique, but however its growing expertise from sophisticated criminals is making the setback of counterfeit medicines an international agenda (WHO, 2006b). This problem of counterfeit medicines has also been encountered in Malta. The media reported a case where a suspected large consignment which was imported in Malta in December 2006, was found to contain counterfeit medicine. Although the medicine was not meant to be sold in Malta, other consignments of the same counterfeited medicine were distributed in other European countries such as the United Kingdom, France and Switzerland (Malta Media, 2007).

While as discussed above EU accession has proved to be beneficial in creating many job opportunities, Malta is now facing the stumbling block of not having enough qualified individuals to cater for all the industry and the regulator's demands. The new pharmaceutical activity required specialised personnel which was lacking in Malta. The most notorious example of this was the case of Qualified Persons (QPs) which are mandatory for Goods Manufacturing Practice (GMP). It was claimed that the salaries requested by QPs (which are currently of a very limited number) were exorbitant and stakeholders claimed that these costs were assimilated in the increases in prices for medicines. WHO (2005a) stated that human resources require global and national co-operation approaches across countries and international institutions, to improve and strengthen health systems. Human resources play a central role in all health systems and this dependence is at times considered as an implication because as technology advances very few jobs get replaced since these improvements require additional specialised and trained staff (WHO, 2006c). Some local manufacturers are getting foreign QPs and some of the local QPs went abroad to gain experience.

The brain drain concern was also an issue which emerged in this study, whereby participants stated that Malta is exposed to loose qualified people because they are leaving the country seeking better job opportunities since accession into the EU made it easier for professionals to emigrate. According to a report issued by the UN Populations Fund, an increasing number of Pacific Islanders are migrating to live, study or work abroad; subsequently their countries are losing qualified citizens and have to take action on the negative impacts to avoid any long term effects. Professional and qualified people such as engineers, doctors, and teachers amongst others seek to find better prospects elsewhere due to shortage of opportunities in their native countries stemming from unemployment, declining economies and low paid jobs amongst others (Singh, 2007).

2.3 The Significance of the Small Size of an EU/EEA Member State and its Implications Upon the Adoption and Implementation of EU Legislation

Section 2.3 explained factors specific to small states and their effect on Medicines Policy. The significance of these factors on the implications resulting from the adoption and implementation of EU Legislation were evaluated on the basis of the information available for Malta, Cyprus and Iceland.

2.3.1 Small size, remoteness and their vulnerabilities

As small island states Malta, Iceland and Cyprus face challenges which are common to all small states, such as the small size of the country which makes the market unattractive, a small economy and lack of human resources. As small states within the EU and EEA, Malta, Cyprus and Iceland face challenges which are unique not only because they are small, but also because they are islands. The problem of isolation adds more pressure to these islands because they are highly dependent on the import and export sectors.

Striking themes which emerged in this study were those of 'smallness' and of a 'small market, whereby the impacts described in this study covered mainly economic issues, limited financial resources, human resources, lack of expertise and seclusion. The impacts of these vulnerabilities particularly the lack of availability of medicines and the relatively high prices of medicines were common to all three small states covered by this study.

2.3.2 Small economies and their implications

The availability of medicines may lack in small states since companies might not think it is worth the expenses, especially if the market is small and unattractive (WHO, 2005b). Pharmaceutical companies lacked interest in investing and exporting their products to small markets because of economies of scale arising out their small size, they considered small markets as risky.

The information available on population and availability of medicines supports the notion that small size affects the availability and the number of authorised products on the market. One of the strategies introduced in the EU legislation to provide a solution for the lack of availability of medicines on small markets was the introduction of the authorisation in line with article 4(2) of the Medicines Regulations in accordance with article 126(a) of Directive 2001/83/EC and as amended by Directive 2004/27 EC of the European Parliament which is also known as the 'Cyprus Provision'. Article 126(a) is a method whereby an EU/EEA member state can authorise products which are already authorised in another EU/EEA member state, through this simplified procedure. This could be a method how the problem of access to medicines can be addressed in small EU/EEA states, to minimise the problems stemming from the small size of the island. Up to now Malta and Cyprus are making use of these provisions to counteract their problems of availability and they are thus trying to exploit the advantage of being part of one large market.

2.3.3 Policy approaches for small states

Briguglio *et* al (2006) stated that the success of small states to implement an outward oriented approach is dependant on reform processes such as enhancing regional cooperation and in building resilience mechanisms to counterbalance their vulnerability amongst others. The EU has in place a comprehensive system in the regulation of medicines, with the scope to ensure that the medicines which are placed on the common market meet the rigorous standards of quality, safety and efficacy (High Level Group on Innovation and Provision of Medicines, 2002). Being part of the common

market should offer the small EU/EEA member states the advantage of being able to co-operate with the other member states.

Crowards in Briguglio & Kisanaga (2004) describes how small states find it difficult to formulate policies because they are vulnerable and experience constant economy shocks. Consequently, studies should focus on the country's individual characteristics and vulnerabilities. However, although the ideal scenario would be to adapt policies which are specific to a country's needs, this was not possible for the small states which acceded into the EU. Malta, Iceland and Cyprus had to adopt the full EU legislation with regards to medicinal products without having an option to adapt the legislation to their own characteristics. This is one of the main problems encountered by small states on accession into the EU. On the other hand with regards to areas of the NMP, which are not covered by EU legislation such as reimbursement and supply through national health services and rational medicines use, these member states had the advantage of being able to set national policies which they considered to be adequate for their needs. In the case of reimbursement and supply of medicines through the national health services Malta and Cyprus adopted a centralised approach including national centralised procurement by tender. On the other hand, Iceland adopted a decentralised approach with supply being totally delegated to private pharmacies.

2.3.4 Strategies for sustainability

There are different opinions on strategies for sustainability particularly with regards to supply of medicines through national health systems. The concept of decentralisation is based on the fact that smaller organisations are more accountable, agile and properly structured when compared to larger organisations. Many countries across Europe have introduced decentralised strategies in their restructuring processes, particularly in the health sector (Figueras *et al*, 2007). On the other hand Dukes *et* al (2003) recommended that the procurement for an entire public health service should be nationally centralised.

Policy options for small states are constrained by their resources (Schiff, Unknown), and therefore centralisation offers small states the advantage of being able to streamline their resources. The fact that the market is small makes centralised systems more manageable. This supports Malta's and Cyprus's option for a centralised system.

The Government's budget of small states is influenced by the population size and its Gross National Product (Ratanawijitrasin & Wondemagegnehu, 2002). Although being small states, Malta and Cyprus are the only EU member states which have no systems for co-payment. As pointed out by the participants in this study, Malta needs to consider the adoption of measures to support the sustainability of its national health system. Political pressures maybe a factor why Malta and Cyprus have delayed the introduction of measures for sustainability.

2.3.5 Competitiveness and integration in the global economy

Von Tigerstorm (2005) considered that small states have limited opportunities for diversifications which leaves their producers economically vulnerable to external fluctuations beyond their control due to the small land area and their typically narrow range of resources and services. Moreover, the lack of resources and the increased costs of transportation due to isolation, may limit the competitiveness to small states (especially if they are islands) for manufacturing. However, accession into the EU and forming part of the EU 'single market' have given Malta and Cyprus an increased ability to export the medicinal products which are locally manufactured because of the status and international recognition of their Drug Regulatory Authorities.

Small states are handicapped by their small markets and small economies and the tendency is that foreign companies are not interested in investing in small markets, unless they can acquire monopolistic advantages (Briguglio et al, 2002). Malta, Cyprus and Iceland have experienced a growth in the manufacturing of generic medicines. This was mainly a result of the fact that for a period of time, many branded manufacturers did not bother to register patents for their products in small states. Generic manufacturers are taking advantage of this lack of registration because it gives them the opportunity to place their products on the market more quickly.

One of the main limitations faced by small states was the lack of resources in particular human resources and laboratory services to support local manufacturing.

2.3.6 Problems with resources

As stated above small states are constrained by their limited resources (economical and human resources), and an interesting issue which both Iceland and Malta have demonstrated is that there are no laboratories available for the quality testing of pharmaceuticals, and both Malta and Iceland use foreign countries for testing. The issue of smallness creates implications because small states have to spend the same amount of money as per larger countries for the same 'procedures' although for a much smaller population.

Moreover the limitations in the provision of training may hinder the availability of adequately trained personnel. For example Cyprus is in the process of establishing a medical school, since up to now training of health care professionals was only accessible through Universities abroad. The lack of adequate educational opportunities to support the evolving requirements introduced by the implementation of the EU legislation in Malta were also highlighted by the participants of the study.

2.4 Conclusion and Recommendations

Whether Malta would have benefited from a different model of medicines regulation which was more adapt to its special characteristics is debatable and is highly dependant on the perspective and the interests of the stakeholder concerned.

With the adoption and implementation of the EU pharmaceutical legislation Malta has beyond doubt reaped positive fruits, particularly from a public health point of view when considering that prior to accession, regulation on medicines was practically non-existent and medicines on the local market did not have the adequate regulations to ensure that medicines on the market are safe, of good quality and efficacious. The manufacturing industry is blooming and creating job opportunities.

This dissertation has shown that the salient characteristics of small states (especially if they are islands) such as remoteness, economic vulnerability, population size, small markets and human resources were also characteristics which prevailed in the Medicines Policy to regulate medicines and pharmaceutical activities. The results are not desirable since lack in the availability or affordability of medicines, are hurdles to public health, and consequently need effective strategies to overcome these vulnerabilities.

This study has proven that small states are susceptible to various implications and limitations, which makes them vulnerable and makes it difficult to implement the legislation of a larger community. Malta, Cyprus and Iceland face common vulnerabilities and share the similar characteristics of a 'small island state', such as the small population size, lack of human resources and lack of finances to implement certain initiatives. The most significant impact of these

vulnerabilities are the lack of availability of medicines and the high increase in prices. It is highly recommended that these small states find means to use the services and benefits of the larger community to solve their problems with availability and affordability. Malta needs a focused strategy to ensure that the medicines on the local market actually meet the demands of the population. As per initiatives taken in other areas, Malta can take the lead and voice the concerns of the negative impacts on small states, and possibly be able to influence EU policy. Malta and Cyprus should use their status as full members of the EU, to press for more provisions in the legislation to cover the needs for small states.

Part of the hostility of pharmaceutical stakeholders towards EU accession could have resulted from what participants considered to be a lack of consultation and involvement during the negotiations. It is important that a lesson is learnt from this experience and stakeholders are informed and included in future policy decisions. Areas of the NMP which should be prioritised for policy development include medicines financing and reimbursement. Participants from the general public in this study have also indicated that there is lack of information in the medicines financing sector.

More information should be made available to the public so as to make the public more conscious of the problems with sustainability and to find a way for the introduction of measures which may not be popular. Any initiatives towards decentralisation in our healthcare system should be well evaluated prior to implementation so as to avoid negative impacts.

One of the main constraints for the expansion of the pharmaceutical industry is the lack of specialised professionals. Participants in this study have raised their concern that our educational system is not offering enough or up-to-date courses to meet the demands of the regulator and the industry. Subsequently, our educational system needs to assess the current needs and re-shuffle courses starting from 'A' Level to University level. Initiatives to motivate local professionals and limit 'brain drain' should be considered.

It is recommended that there is an educational campaign for the general public to cover medicines rational use and on Medicines Policy in general. Participants in this study have shown that the general public did not have enough information on the subject. One area to be prioritised is the inter-changeability of products with the same active ingredient (generic substitution). The public should be empowered to take decisions regarding the most cost effective choice of medicines. This should compliment the role of the healthcare professionals. The negative publicity on the decrease of availability of medicines, and in the increase in the prices of medicines, may influence the public's opinion and acceptance of educational campaigns.

The WHO and the EU legislation provide a separate framework to protect the environment; however, these are not implemented into Medicines Policy strategies. In fact the situation in Malta replicates the problem identified within the EU legislative framework in that the environmental aspects were not included in the legislation specific to medicines. Malta took the lead in several initiatives and proposals which led to various adoptions of conventions, whilst placing the small island states on the agenda in the field of economic vulnerability in the global community. This can be another initiative from a small state and to take the lead to encourage environmental approaches to be adopted in all areas of policies (including that of medicines), at national, regional and at a global level.

One of the difficulties encountered in this study was the lack of information on Medicines Policy in other small states in different regions of the world. Further studies and sharing of information is vital for small states, since they share similar vulnerable characteristics, and learning from other small states is ideal in both implementing the positive aspects and avoiding the negative outcomes.

Three years post EU accession, any possibilities of changing the position taken during negotiations is highly remote. Thus, it is recommendable that the small EU/EEA states join forces and focus on how to participate within the EU regulatory framework to influence decisions in order to ensure that their needs (which are particular to their special characteristics arising from the fact that they are small) are addressed so that the vulnerabilities and risks are minimised.

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